

Medi-Cal Pharmacy Program

AVERAGE SALES PRICE
INFORMATION MEETING

APRIL 8, 2005

Introductions

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Welcome

- Thank you attending
- Discussion Reminder

Participants are reminded that we are in a group setting and must consider the potential for antitrust implications when engaging in discussion.

- Why we are here
 - Welfare & Institutions Code Section 14105.45

OVERVIEW

- Background
- California Statute
- Discussion of Average Sales Price
- Reporting format and attestation
- Implementation timeline
- Next steps
- Questions

Background

- ASP – Average Sales Price
- First added to CA statute in 2002
- Language was “placeholder”
- Conveyed Medi-Cal’s intent
- Response to Qui Tam lawsuits on federal false claiming issues
- “Toothless” – did not compel manufacturers to comply

Section 14105.45

- Budget Health Trailer for 2004
- Reduced reimbursement to pharmacy providers from AWP minus 10% to 17%
- Refined language on ASP
- Pre-dates final federal rule on ASP
- Provides permissive penalty for manufacturer non-compliance

•Reduced reimbursement: effective 09/01/2004

•Permissive penalty for manufacturer non-compliance: 14105.45(c)(3) For manufacturers that fail to provide average sales price information pursuant to this section, the department may subject their drugs' availability to prior authorization. The provisions of this subdivision shall be included in contracts or contract amendments entered into by the department pursuant to Section 14105.3, 14105.33, 14105.37, or 14105.39, and **manufacturers shall continue rebate payments** according to the rebate provisions in the contracts. Nothing in this paragraph shall affect a Medi-Cal beneficiary's ability to receive continuity of care for 60 days as contained in subdivision (i) of Section 14105.33.

ASP Defined

(1) "Average sales price" means, of a drug or biological, the sales price for a National Drug Code for a calendar quarter for a manufacturer for a unit, calculated as follows:

- Medicare final rule
- CA statute
 - Change to be consistent with Medicare
 - May include “class of trade” reporting
- Input from all concerned

• Final Federal Rule – Manufacturer submission of ASP data for Medicare Part B drugs and biologicals: Federal Register/Vol.69, NO. 179/Thursday, September 16, 2004/Rules and Regulations

• Medicare Part B Drugs Average Sales Price (ASP) Information Resource: <http://www.cms.hhs.gov/providers/drugs/asp.asp>

• Today Medi-Cal reimburses *Anti-Hemophilia factors* using the lower of the manufacturer's Average Selling Price (ASP) plus 20 percent or the provider's usual and customary charge. (http://files.medi-cal.ca.gov/pubsdoco/publications/masters-MTP/Part2/bloodhcfa_m01p00.doc)

ASP Calculation

- Multiple methods of calculating?
- Desire - one “method” nationally
- Provider concern with inclusion non-retail entities
- Class-of-trade potential
- DHS will follow Medicare calculation for lagged and non-lagged price concessions
- DHS will issue guidance as it proceeds

Which Products

- TEST – Is it sold in the United States?
- No restrictions on product class or dosage form
- Includes all drugs and biologicals regardless of federal rebate status
- What about vaccines?

Test: Is it sold in the United States? – US sales do not include sales in the commonwealth territories, trust territories, and protectorates.

Yes, includes vaccines...

- Address issue of pediatric vaccines??? – comment from mfg: pediatric vaccines are made available to Medi-Cal beneficiaries through participating physicians and purchased under federal contract at low prices...
 - Already exempt from ASP calculation to the extent that the sale of the vaccines meets the criteria set forth in 14105.45(a)(1)(B)(i): Sales exempt from inclusion in the determination of “best price” under Section 1927(c)(1)(C)(i) of the Social Security Act (42 U.S.C. Sec. 1396r-8(c)(1)(C)(i)).
 - Vaccines administered by a pharmacist
 - Future plans for changes in physician/clinic reimbursement???

Which Sales Included

- Starting point is Medicare
- Consideration for class of trade due to differences between medical and retail pharmacy sales practices
- Wholesaler service fees – unknown
- Medicaid exempt sales not included
- Based on sales in the United States

- Wholesaler service fees:

- CMS allows for exemption of bona fide service fees as defined in the Code of Federal Regulation (42 CFR Part 414 Subpart J, 414.804) from the ASP calculation.

- US sales do not include sales in the commonwealth territories, trust territories and protectorates.

- We will look at class of trade issues. Test data required for DHS to be able to research/evaluate impact of class of trade on ASP and development of final guidance. Would require change in statute.

Reporting

- Based on the 11-digit NDC (same as reimbursement)
- Certification will be required – by whom and frequency has yet to be determined
- Reported to DHS or designated agent
- Electronic process
- Quarterly reporting (30-days after end)

Quarterly reporting: W&I 14105.45(c)(1): Manufacturers and principal labelers of legend and nonlegend drugs shall, no later than 30 days after the end of each calendar quarter, and in a format determined by the department, provide to the department the average sales price of each of the manufacturer's legend and nonlegend drugs.

Current frequency of reporting same as Medicare.

Other issues to take into consideration when evaluating monthly vs. quarterly ASP reporting:

- mid-quarter price changes
- mid-quarter new drug approvals

Suggested Data Layout

AVERAGE SELLING PRICE (ASP) LAYOUT

Header

Manufacturer name	SUGGESTED LAYOUT
Manufacturer address	
Contact person	
Phone number	
E-mail address	
DATE	
NUMBER OF LINE ITEMS REPORTED	

NDC	Product Description	Package Size	ASP per unit	Unit of Measure	Start date of ASP reporting period	End date of ASP reporting period
11 digit NCPDP formatted code	alpha-numeric, 60 characters	numeric 12 characters 9(8).9(3) (explicit decimal point)	numeric 12 characters 9(6).9(5) (explicit decimal point)	MUST follow NCPDP Billing Unit Standard	First day of reporting quarter	Last day of reporting quarter
alpha-numeric 11 characters	only used in QCs	MUST follow NCPDP Billing Unit Standard	MUST follow NCPDP Billing Unit Standard		numeric 8 characters, YYYYMMDD	numeric 8 characters, YYYYMMDD

Full file each time NDC's that have an effective date (e.g., NOT zero date/zero price). If prices go to zero, we do then need the date+zero price record.
 Delimited text file is best (no Excel, no PDF) with fixed length fields (using Standard Product terms, "RELD" not "RELDV" format)
 Electronic format (e.g. download or CD)
 Headers are not useful to us. If we have a standard format, then we know what's in each column.

Looking to make process electronic, but will consider impact on small manufacturers that may find this requirement too cumbersome.

Compliance

- Statute requires compliance or....
 - “For manufacturers that fail to provide average selling price information pursuant to this section, the department **may** subject their drugs' availability to prior authorization.”
- Permissive, not mandatory
- Errors – can ASP be corrected?
 - Unknown - difficult in a real-time system
 - May depend on when correction occurs

How is ASP used

- "Selling price" means the price used in the establishment of the estimated acquisition cost. The department shall base the selling price on the average sales price reported by manufacturers pursuant to subdivision (c). The selling price shall not be considered confidential and shall be subject to disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).
- Selling price gives DHS rate setting leeway
- ASP used as the starting point
- DHS will look at multiple factors when setting a pharmacy rate

How is ASP used

- Use of selling price allows for adequate payment when ASP is lower than pharmacy acquisition cost
- Protection of ASP confidentiality
 - Reverse engineering from Selling Price
 - Unknown at this time
- ASP will not be used in calculating rebates unless federal statute changes to do so

How is ASP used

- ASP may be used for other programs in the future
- Will affect both Workers Compensation and SB393 since both programs point to Medi-Cal reimbursement rates

Other Issues

- Waiver to use ASP not required
- State plan doesn't reflect ASP use
- DHS will submit a State Plan Amendment when implementation date is known
- Dispensing fee – change may or may not occur – will be discussed with providers
- Contracts – not needed, but may still occur to memorialize finer points not in statute

Other Issues

- Why not use AMP?
 - Highly confidential
 - Industry was opposed when statute first passed
 - AMP doesn't capture all market segments that may apply
- What if ASP isn't reported? Use WSP that will be obtained from wholesalers

Timeline



Projected timeline for full implementation of ASP reporting: 1st quarter 2007.

Some factors influencing timeline:

- Possible statutory changes.
- Possible need for systems changes.
- Need to collect test data from manufacturers to facilitate the develop of final guidance for the ASP calculation.
- Need to submit a state plan amendment.
- Updated information will be posted on this website as it becomes available.

Next Steps

- Disseminating information
 - Website: <http://dhs.ca.gov/pharmacy>
 - Email for additional questions: ASP@dhs.ca.gov
 - Individual meetings – only if absolutely needed for proprietary issues that cannot be handled by correspondence
- Follow-up meeting in the future
 - Future meeting will make telecommunications an option

Website address: <http://dhs.ca.gov/pharmacy>

E-mail address: ASP@dhs.ca.gov (non-ASP related email will not be responded to, please use **P.O. Box 997417, MS 4604, Sacramento, CA 95899-7417** for non-ASP correspondence.)

Next Steps

- Meeting with Wholesalers
- Meeting with Pharmacy Providers
- Follow-up statutory changes
- State Plan changes

QUESTIONS